Attorney Docket No.: 10527-118004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Kevin R. Heath	Art Unit	: 3738
Serial No.	: 09/924,275	Examiner	: H. Phan
Filed	: August 8, 2001		
Title	: TUBULAR MEDICAL ENDOPROSTHESES		

Commissioner for Patents
Washington, D.C. 20231

PETITION TO EXPUNGE PROPRIETARY MATERIAL UNDER 37 CFR §1.59

Petitioner submitted by hand delivery to the Examiner on June 28, 2000, proprietary materials pursuant to M.P.E.P. §724. If after review of these documents by the Examiner the proprietary materials are found not to be important to a reasonable Examiner in deciding whether to allow the application to issue as a patent (See M.P.E.P. §724.04(a)), Petitioner hereby petitions to expunge the proprietary materials pursuant to 37 C.F.R. §1.59.

In accordance with M.P.E.P. §724.05: Petitioner states that the materials are proprietary and have not otherwise been made public; Petitioner commits to retain the proprietary materials for the period of any patent with regard to which the proprietary information is being submitted; and Petitioner states that the Petition to Expunge is being on behalf of the party in interest who originally submitted the information.

A check for $130 in payment of the fee required under 37 CFR §1.17(i) is enclosed. Please apply any other charges or credits to Deposit Account No. 06-1050.

01/23/2003 THARGROV 00000001 09924275
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CERTIFICATE OF DELIVERY BY HAND

I hereby certify that this correspondence is being delivered by hand on the date indicated below and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

12/19/02
Date of Delivery

Ann Rutledge
Signature

Ann Rutledge
Typed or Printed Name of Person Signing Certificate

Respectfully submitted,

Date: December 17, 2002

Sean P. Daley
Reg. No. 40,978

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

20550341.doc

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Commissioner of Patents
Washington, D.C. 20231

TRANSMITTAL OF DOCUMENTS VIA HAND DELIVERY

Enclosed herewith are the following documents:

1. An envelope of Proprietary Material so-labeled;
2. One Box of Proprietary Material so-labeled;
3. Petition to Expunge Proprietary Material Under 37 CFR § 1.59 with required fee ($130.00);

Please apply any charges not covered, or any credits, to Deposit Account No. 06-1050.

Respectfully submitted,

Date: December 17, 2002

Sean P. Daley
Reg. No. 40,978

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Assistant Commissioner for Patents
Washington, D.C. 20231

REMARKS REGARDING MATERIAL SUBMITTED UNDER SEAL PURSUANT TO MPEP §724

A petition to expunge this document from the file, along with the exhibits and other documents, is attached.

Introduction

Attached hereto are proprietary internal documents that demonstrate work at Schneider (USA), Inc. ("Schneider") toward the development of stents, including stents with enhanced radiopacity. The assignee of the present application came into possession of the documents through the purchase of Schneider and, to satisfy any possible issues regarding the duty of disclosure, is submitting this information so that the examiner can consider whether the work of Schneider is material to the patentability of the present application.[1]

Below, we provide a discussion of our understanding of the Schneider work. Our understanding is formed after review of the documents and discussions with David Mayer, the lead engineer and named inventor on Schneider's enhanced radiopacity patents. Our comments about our understanding should not be taken as admissions.

[1] As used herein, the phrases "work of Schneider" and "Schneider work" refer to the work performed on radiopaque stents by employees of Schneider.

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For the reasons discussed below, it appears that the work at Schneider is not material to the patentability of the present application and should be expunged from the file in accordance with M.P.E.P. §724.05.

Mayer's reduction to practice

Mayer did not achieve constructive reduction to practice prior to the present application ("Heath"). Constructive reduction to practice occurs upon filling of a patent application. Hazeltine Corp. v. United States, 820 F.2d 1190, 1196 (Fed. Cir. 1987) ("the filing of a patent application is a constructive reduction to practice."). The constructive reduction to practice of the Heath application occurred on March 31, 1992, and for features supported by a CIP, on July 8, 1992. Mayer's patent application was filed well after the Heath applications. Mayer's application was filed January 19, 1993 and has now issued as US Mayer U.S. 5,824,077 (several related cases have also subsequently issued). As a result, based on their respective filing dates, the Heath filings have prima facie priority over Mayer's filings.

Nor does it appear that Mayer had an actual reduction to practice prior to the Heath constructive reduction to practice. Actual reduction to practice requires that an invention be sufficiently tested to demonstrate that it will work for its intended purpose. Kimberly Clark Corp. v. Johnson & Johnson 745 F.2d 1437 (Fed. Cir. 1984). The character of the testing varies with the character of the invention and the problems it solves. Scott v. Finney 34 F.3d 1058 (Fed. Cir. 1994). Testing need not show utility beyond the possibility of failure but only utility beyond a probability of failure. Id. Complex inventions and problems in some cases require laboratory tests that accurately duplicate actual working conditions in practical use. Elmore v. Schmitt 278 F.2d 510, 513 (CCPA 1960). In the case of life-critical devices which are implanted in humans, the requirement of the testing is usually quite severe. See Nelson v. Bowley, 626 F.2d 853, (CCPA 1980); Medtronic, Inc. v. Daig Corp., 611 F.Supp. 1498, (D. Minn. 1985), aff'd, 789 F.2d 903, (Fed. Cir. 1986), cert. denied, 479 U.S. 931 (1986) (no reduction to practice

of lead for pacemaker absent tests by implantation in humans; tests on dogs, while valuable for research, are not sufficient to show operability in a human heart); Samson v. Crittenden, 14 USPQ 2d 1810, 1814 (Bd. Pat. App. & Int'f 1989) (limited animal testing; the device falling within the interference count "was not tested under actual use conditions or under conditions that would simulate use conditions as required for an actual reduction to practice." expert's opinion testimony that "the device would work, as intended, if used on human cannot take the place of evidence in the record."); Antoshkiw v. Pevsner, 224 USPQ 1049, 1051 (Bd. Pat. Int'f. 1983) (miniature balloon catheter assembly for use in small vessel diagnostic and therapeutic procedures: "There is no evidence ... That the device was tested in humans let alone satisfactorily tested therein ... [The] contention that merely making a device in the form depicted ... or testing it in dogs is sufficient for a reduction to practice is without merit."). An exception is when the invention solves a problem related to an uncomplicated aspect of the device. See Scott v. Finney 34 F.3d 1058 (Fed. Cir. 1994)

As appears from the attached documents and discussions with Mr. Mayer, the work at Schneider was directed to a medical prosthesis, known as a stent, that is implanted inside a body lumen. The stent has a generally tubular shape which abuts the inner walls of the lumen to help hold the lumen open. The particular stent that they were working on was a tube defined by a braided wire mesh. A character of the stent was that it was self-expanding, i.e., it could be compressed into a small diameter for delivery into the body on catheter and then expanded to lumen diameter by virtue of its own elastic forces. Once in place, the stent must maintain its integrity. Failure could have severe consequences for the patient.

The feature of the stent that Mayer sought to modify was the very wire from which the stent was made. Conventional wire was made of metals that were highly elastic, which gave good mechanical performance. But highly elastic metals were typically not very radiopaque, meaning that the stent was difficult to see by fluoroscopy as the physician placed it

in the body. Mayer sought to improve the radiopacity by investigating several techniques, including making the stent out of a coaxial composite wire or cored wire that included a tubular "cladding", made of elastic metal, which surrounded a "core" of a more radiopaque metal. The goal was to balance the mechanical property of the elastic metal with the radiopaque enhancement of the core to provide a stent that was mechanically sound, had enhanced radiopacity, and was biocompatible. This is described in the Schneider Idea Record prepared by David Mayer:[2]

> This concept is designed to take advantage of specific crucial material characteristics relating primarily to a braided self-expanding stent structure for human implantation. The desired goal is to balance radiologic imaging behavior, at implant and subsequent follow up evaluations, with mechanical performance and bio-/hemocompatibility. The fundamental wire is composed of multiple materials layered in concentric fashion to achieve a satisfactory balance between radiopacity, mechanical spring properties, corrosion and stress fatigue failure resistance, general material (i.e., non-hemolytic, non-thrombogenic, anti-proliferative surface morphology, etc.), cost, and manufacturability. Type A is the least complex to fabricate, can present the identical material to the implant site as the current homogeneous material (i.e., Elgiloy®/Phynox®), and offers substantial mechanical protection to certain highly ductile, soft, but significantly more radiopaque core materials.

The new composite wire is largely referred to in the documents as "drawn filled tubing" or "DFT", a name used by Mayer's wire supplier, Fort Wayne Metals. To determine whether the new composite metal system could be successful in a stent, Mayer required several

[2]One copy of the Idea Record carries a date of October 18, 1989 on the first page, but is not signed or witnessed. Another copy of the Idea Record is identical except that it bears a date of signature of February 20, 1992, and a date of witnessing of March 23, 1992. Both copies of the Idea Record are attached as Exhibit A.

types of tests.[3] One type of test involved mechanical testing of the wire and the stent made of the wire using many different combinations of wire diameters and core diameters. These tests involved mechanical manipulation over many repetitive cycles to determine at what point the wire would fail. Another type of test was to demonstrate the biocompatibility of the new wire. This appears to be a particular concern due to the possibility that the two different metals in the new wire system might undergo galvanic corrosion inside the body.

In 1990, 1991, and 1992, it appears that Mayer tested wire and/or prototype stents using various combinations of metals for the clad and core. For the clad, the investigations focused primarily on two materials-- an alloy known as MP35N® and an alloy known as Elgiloy® (sold overseas as Phynox®). Preliminary experiments were conducted using MP35N® because it was more readily available in composite form than Elgiloy®. In late 1991, the preliminary experiments with MP35N® composites were discontinued when Elgiloy® composites became available.

At least by April 1992, it appears that there had not been sufficient testing to conclude that the stent made of Elgiloy® composite wire would be successful. In a March monthly report dated April 1, 1992, and attached as Exhibit B, the status of the project was summarized as follows:

> Radiopacity:
> The wire for the DFT enhanced radiopacity program is starting to come in. Both the 0.0047 and 0.0055 in 10% Tantalum wire is in stock. Wire has been braided and is undergoing wire spin fatigue analysis at this time. Twenty-five percent wire is due within weeks and the 45% coronary wire is due in early May. We are ordering

[3] See, e.g., Mayer's Idea Record (Exhibit A) ("The fundamental wire . . . [should] achieve a satisfactory balance between radiopacity, mechanical spring properties, corrosion and stress fatigue failure resistance, general material biocompatibility, specific hemocompatibility (i.e., non-hemolytic, non-thrombogenic, anti-proliferative surface morphology, etc.), cost and manufacturability").

> the platinum wire for the small size coronary wire due to the inherent question of whether 45% Tantalum will compromise the mechanical and expansive properties of the stent. Biocompatibility specimens of the Tantalum/Elgiloy wire will be sent to NAmSA next week, with long-term implant results at one week, one month, three months, and six months.
>
> If the 10 or 25% Tantalum core wires pass the mechanical testing, testing for a 510(k) for biliary will be complete in June. Biocompatibility will be the hold up for the IDE submission as full tripartite data is required. The reason biocompatability could not be started sooner was because we could not obtain material processed in accordance with manufacturing techniques required by the stent. This is the first material (Elgiloy-cased DFT) of this type and spring temper developed at Fort Wayne.

Subsequently, it appears mechanical testing was carried out. But by July 8, 1992, the filing date of Heath, it appears that the analysis of the mechanical testing was still incomplete. In a memo dated July 6, 1992, and attached as Exhibit C, Mayer called a meeting to be held July 10, to discuss the "initial" analysis of the fatigue tests conducted by an outside consultant:

> July 06, 1992
>
> Friday 10 July 1992
>
> A related secondary topic will be the initial comparison analysis of the current Elgiloy solid wire fatigue with the Elgiloy `DFT' tantalum composite for radiopacity enhancement.

The analyses to be presented at the meeting were, we understand, statistical studies of the fatigue test data that were necessary to appreciate whether the stents were to be successful. As a result, there could be no reduction to practice at least until these results were presented to and considered by Mayer, which does not appear to have occurred until the meeting on July 10, 1992. See Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588, 594 ("there must be

recognition and appreciation that ... tests were successful for reduction to practice to occur"; no reduction to practice until consultant's results were communicated and analyzed.)

In addition, the biocompatibility testing was incomplete, as indicated by the fax message from David Mayer to NAMSA, the testing agency, dated August 4, 1992, and attached as Exhibit D. The first product was a biliary stent, for which regulatory approval was sought in August, 1992. The product was not introduced until 1994.

The foregoing facts were discussed with Mr. Mayer. He did not dispute these facts. He stated that he felt that he knew all along that the composite stent would work. But, he also said that he did not keep a daily report of the Schneider work, and that without such daily reports it would not be possible to determine the day-to-day development of the Schneider work.

As a result, it does not appear that Mayer achieved an actual reduction to practice prior to the constructive reduction to practice by Heath.

Mayer's diligence

Notwithstanding that Mayer did not achieve reduction to practice prior to Heath, the Schneider work could still be relevant if Mayer was diligent from a time just prior to Heath's conception until Mayer's own reduction to practice. Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578 (Fed. Cir. 1996). Diligence requires that the inventor account for the entire critical period by showing either activity aimed at reduction to practice or legally adequate excuse for inactivity. Griffith v. Kanamaru, 816 F.2d 624, 626 (Fed. Cir. 1987). The burden of proving such diligence would be on Mayer. Behr v. Talbott, 27 U.S.P.Q.2d 1401, 1405 (Bd. Pat. App. & Int. 1992).

The conception by Heath is evidenced by the invention disclosure (Exhibit K). The date of this document is prior to March, 1991. As a result, Mayer would have to show diligence from a time just prior to Heath's conception until Mayer's own reduction to practice, which is after Heath's constructive reductions to practice 17 months later, as discussed above.

While in general there appears to be a lack of proof as to whether Mayer was working diligently on the composite, cored-wire stent over the critical period of time, there is at least one portion of this time period during which it appears that Mayer was not working on the composite, cored-wire stent at all. In particular, there appears to be a gap in activity toward reduction to practice of the composite, cored-wire stent in the March-April, 1991 time frame. In this time-frame, it appears that, rather than working on a radiopaque stent formed of a composite, cored-wire, Mayer focused on increasing radiopacity by the very different technique of interweaving a solid wire of a radiopaque metal into the mesh of a conventional wire.

The use of a composite, cored-wire was one of several avenues Mayer investigated to attempt to enhance radiopacity. In the document entitled "Hospital Products Group 1991 Major Projects", dated November 1990, and attached as Exhibit E, it is apparent that several areas would be investigated:

C. Stent Visibility

> The present stent is difficult to image on x-ray film and very difficult to distinguish using fluoroscopy.

1. Alternate stent materials:

> Evaluation of material known to be more radiopaque as substitute stent materials. Significant challenges involve surface finishing and cleaning as well as suitable resilience to allow adequate deformation for loading onto deployment device.

2. Composite stent structure:

> Coaxial layered wire composites will provide opportunity to create an outer ring of material chosen for biocompatibility and mechanical properties and an inner core chosen for radiopacity.

3. Alternate methods:

Evaluation of potential for using optical interference and cross-polarization will be conducted.

The proposed priority of the projects is also set forth in the same report.

C. Radiopacity

1.	Determine feasibility of alternate homogeneous materials.	1Q/91
2.	Determine feasibility of coaxial wire structure with adequate physical, corrosive and radiopaque properties.	3Q/91

As apparent, the investigation of item number 1, evaluating substitute stent materials, was to be completed prior to the investigation of coaxial composites.

On March 6, 1991, in a monthly report memo attached as Exhibit F, David Mayer indicated that the Elgiloy® tubing had been ordered and that a DFT wire using the other alloy, MP35N® was being quoted. The goal for March was to order Elgiloy® and MP35N® DFT composites:

March 6, 1991

From: Dave Mayer, X5825

Subject: FEBRUARY PRINCIPAL ACTIVITIES

4. Elgiloy® welded and drawn tubing ordered via E.L.P. for `DFT' stent material composite fabrication.

- MP35N® proof-of-concept material being quoted

- Elgiloy® drilled and filled composite being quoted

MARCH GOALS

7. Order two Elgiloy® `DFT' configurations and MP35N® proof-of-concept composite materials.

But it appears from the documents in the March-April time frame that these tasks were delayed by more than one month in order to work on the feasibility of alternate homogeneous materials. According to a fax message attached as Exhibit G, David Mayer did not request the quotation for the MP35N® wire until April 29, 1991. On May 7, 1991, David Mayer finally ordered the MP35N® DFT material from Fort Wayne Metals. (See Exhibit H). The monthly report by David Mayer dated June 3, 1991, and attached as Exhibit I, does not appear to indicate any work on the composite wire in March or April.

During this time, it appears that Mayer focused instead on a different approach to enhancing radiopacity. Rather than a composite wire, monolithic wires made of more radiopaque metals materials were woven into the stent mesh. In particular, stents woven with some wires of solid Elgiloy® and other wires of solid tantalum were tested. For example, in the Laboratory Test Request by David Mayer dated April 15, 1991, and attached as Exhibit J:

> RATIONALE FOR TEST
>
> To evaluate the mechanical fatigue characteristics of stent with tantalum wire substitution of one and two Elgiloy® braid wires. Also evaluate the bimetallic galvanic and fretting corrosion potential at braid overlays or picks.

But this different strategy for enhancing radiopacity by interweaving a tantalum wire into the stent mesh should not be able to excuse the lack of activity toward the reduction to practice of a stent made of cored wire. Hudson v. Giuffrida, 328 F.2d 918, 925 (CCPA 1964) ("Equipment was available for testing and the record amply shows that tests would have been significant and were delayed primarily to avoid interrupting other projects."); English v. Ausnit, 38 USPQ2d 1625, 1638 (Bd. Pat. App. & Int'f 1993) ("Efforts to actually reduce another invention to practice may excuse inactivity with respect to the invention of the count, provided

an actual reduction to practice of that other invention is necessary to enable the invention of the count to be actually reduced to practice."). Amgen Inc. v Chugai Pharmaceutical Co., Ltd., 13 USPQ2d 1737, 1764 (D. Mass. 1989) aff'd in part, vacated in part 927 F.2d 1200 (Fed. Cir. 1991) ("By making the financial decision to pursue the alternative routes ... without seeking outside funding or reinstating negotiations with [the source] earlier, [the prior conceiver's company] assumed the risk that priority in the invention might be lost to another inventor in the interim.").

Other documents in this period suggest work on heat testing Elgiloy® wire. But this work appears to be directed to solid Elgiloy® wire, which was being used in Schneider's then-current products, rather than radiopacity-enhanced stents. A consultant, Richard Peugot, appears to have been conducting a study of the various radiopacity enhancement options. But this does not appear to have been a cause for delay in pursing experiments toward a reduction to practice of the stent made of composite wire.

The foregoing facts were discussed with Mr. Mayer. He did not dispute these facts. He indicated that it was his belief that he was working continuously on the composite wire project. He also indicated that the interwoven data was used only for comparison to the composite wire work. Mr. Mayer further indicated that he did not keep a daily report of the development of the Schneider work, and that without such daily reports it would not be possible to determine the day-to-day development of the Schneider work.

As a result, based on the attached exhibits and other documents submitted herewith, it appears that Mayer was not diligent from a time prior to the Heath conception until Mayer's own reduction to practice. Moreover, it appears that there exists no documents that would contradict this conclusion.

Conclusion

The Schneider work is not material to the patentability of the present application because Mayer did not achieve reduction to practice prior to Heath, nor was there reasonable diligence from a time prior to the Heath conception to Mayer's own reduction practice. As a result, the material submitted under seal should be expunged from the file.

Submitted herewith is a Petition Under 37 CFR § 1.59 to Expunge the Proprietary Material with the required fee.

Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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Schneider

SCHNEIDER STENT

CONFIDENTIAL

Now PC 8376

SD 34

IDEA RECORD

(Use Ink)

Originated by DAVID W. MAYER Log No. 10

Date 10-18-89

1. Title of Idea CLAD COMPOSITE STENT MATERIAL - METAL

2. Describe idea below using numerals to refer to parts in the sketch on the reverse side.

THIS CONCEPT IS DESIGNED TO TAKE ADVANTAGE OF SPECIFIC CRUCIAL MATERIAL CHARACTERISTICS RELATING PRIMARILY TO A BRAIDED SELF-EXPANDING STENT STRUCTURE FOR HUMAN IMPLANTATION. THE DESIRED GOAL IS TO BALANCE RADIOLOGIC IMAGING BEHAVIOR, AT IMPLANT AND SUBSEQUENT FOLLOWUP EVALUATIONS, WITH MECHANICAL PERFORMANCE AND BIO-/HEMOCOMPATIBILITY. THE FUNDAMENTAL WIRE IS COMPOSED OF MULTIPLE MATERIALS LAYERED IN CONCENTRIC FASHION TO ACHIEVE A SATISFACTORY BALANCE BETWEEN RADIOPACITY, MECHANICAL SPRING PROPERTIES, CORROSION AND STRESS FATIGUE FAILURE RESISTANCE, GENERAL MATERIAL BIOCOMPATIBILITY, SPECIFIC HEMOCOMPATIBILITY (i.e., NON-HEMOLYTIC, NON-THROMBOGENIC, ANTI-PROLIFERATIVE SURFACE MORPHOLOGY, ETC.), COST, AND MANUFACTURABILITY. TYPE I IS THE LEAST COMPLEX TO FABRICATE, CAN PRESENT THE IDENTICAL MATERIAL TO THE IMPLANT SITE AS THE CURRENT HOMOGENEOUS MATERIAL (i.e. ELGILOY®/PHYNOX®), AND OFFERS SUBSTANTIAL MECHANICAL PROTECTION TO CERTAIN HIGHLY DUCTILE, SOFT, BUT SIGNIFICANTLY MORE RADIOPAQUE CORE MATERIALS. TYPE II SHOWS A CONFIGURATION OPTIMIZED FOR RADIOPACITY AND OTHER SURFACE RELATED PHENOMENA. TYPES III AND IV SHOW MEANS BY WHICH POTENTIALLY INCOMPATIBLE (e.g. INTERMETALLIC FORMERS) MATERIALS MAY BE ARRANGED TO PERMIT FABRICATION AND SATISFACTORILY PERFORM AS AN IMPLANT.

3. Its purpose or basic advantage THE BASIC ADVANTAGE FOR THE WALLSTENT® SELF-EXPANDING STENT IS THAT THIS COMPOSITE PROPOSAL PROVIDES THE ONLY VIABLE MEANS FOR ALL WIRE ELEMENTS (OR LIMITED INDIVIDUAL NUMBERS) TO EXHIBIT ALL DESIRED PROPERTIES IN AN ACCEPTABLE BALANCE.

DO NOT FILL IN BELOW THIS LINE (DISPOSITION)

NPC File No. Date

4. (a) NPC Action
   - ___ File, Send Response No further action
   - ___ Refer to Research
   - ___ Assign Feasibility Team

PC File No. Date

(b) Patent Committee Action
- ___ Fill out Invention Disclosure
- ___ Reconsider next month
- ___ File, no further action

Date of

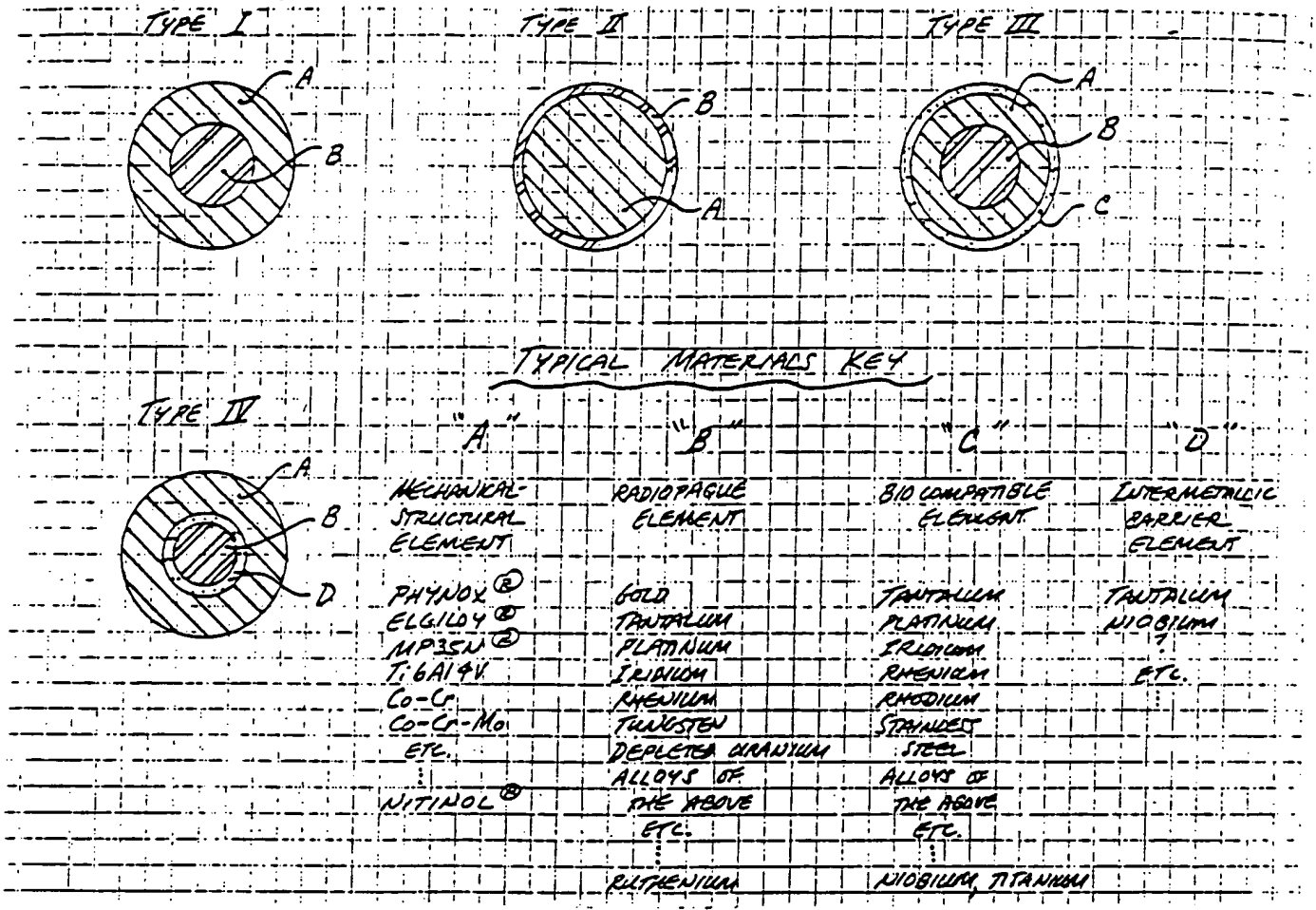
(c) Other
- ___ Send to Research
- ___ Send to Marketing
- ___ Send to Development
- ___ Respond to Originator w/o Further Action

5. Reason for Action: _____

6. Key Words: _____ ; _____ ; _____

PROPRIETARY MATERIAL

7. Sketch (use ink)



8. This idea first came up on or about 25 AUGUST, 1989 under the following circumstances: VIEWING SLIDES OF THE RADIOGRAPHY IMAGES OF ANDY ADAMS, M.D. STENT IMPLANT 08-12-89, LONDON, ENGLAND. THIS PRESENTATION WAS CONDUCTED AT SCHNEIDER STENT ON 08-25-89 BY ALAN MARQUARDT AND GREG SACHS.

9. Other records which substantiate this date are as follows: SUBSEQUENT TELTECH LOCATED EXPERT, DR. JOHN MOORE, BIO-IMAGING RESEARCH, INC., AND TELEPHONE REPORTS AND LETTER FROM DR. MOORE, (BETWEEN 10-31-89 AND 12-11-89), ON RADIOGRAPHIC IMAGING AND MATERIALS.

10. This was read by me and I understand it. (Desirable to use person or persons to whom idea was first disclosed.)

Name _____ Date _____

Name _____ Date _____

11. Submitted by: David W. Mayer Date _____

_____ Date _____

PROPRIETARY MATERIAL

Schneider

SCHNEIDER STENT

CONFIDENTIAL

IDEA RECORD

(Use Ink)

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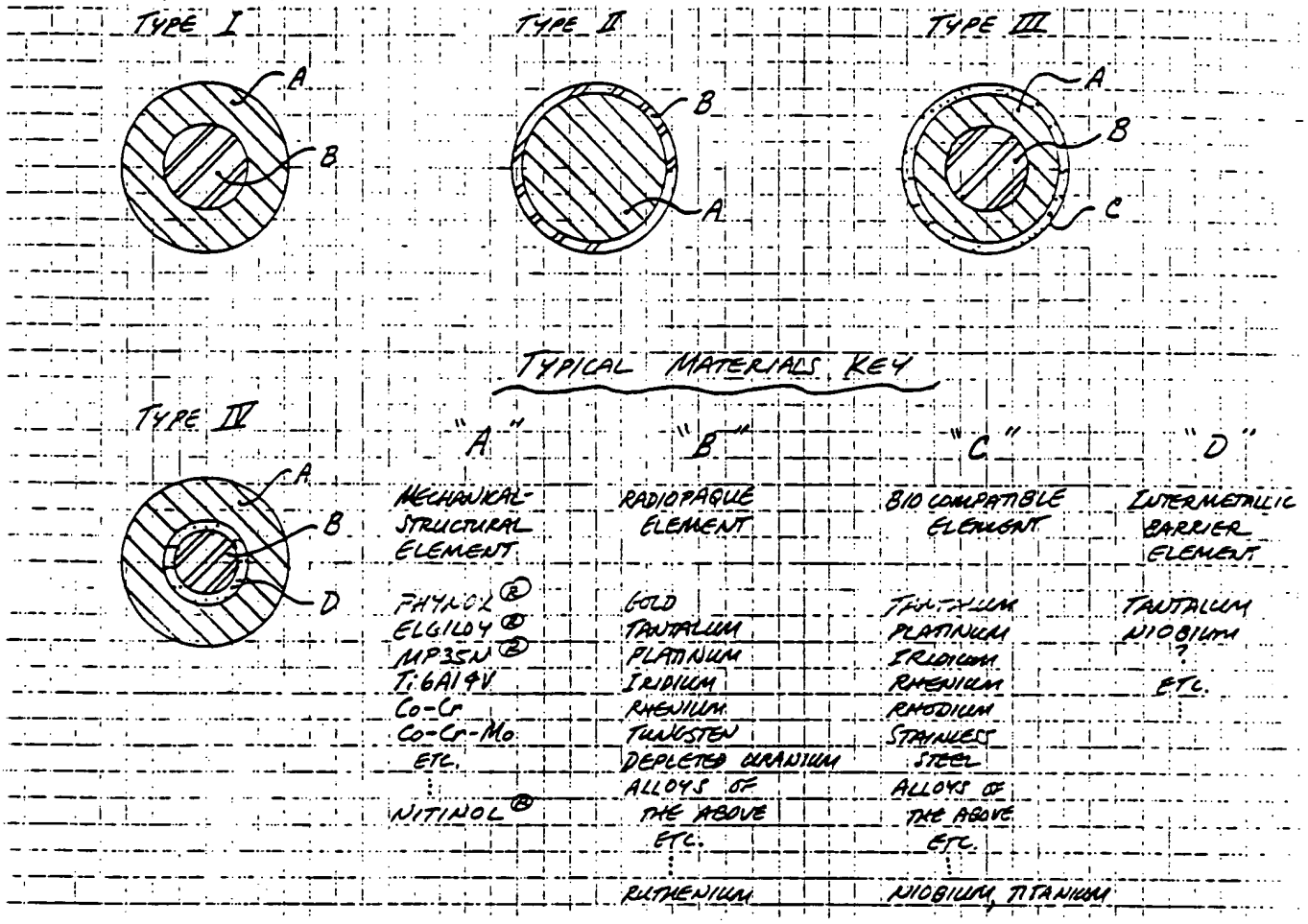
PROPRIETARY MATERIAL

7. Sketch (use ink)



8. This idea first came up on or about 25 AUGUST, 1989 under the following circumstances: VIEWING SLIDES OF THE RADIOGRAPHY IMAGES OF ANDY ADAMS M.D. STENT IMPLANT 08-12-89, LONDON, ENGLAND. THIS PRESENTATION WAS CONDUCTED AT SCHNEIDER STENT ON 08-25-89 BY ALAN MARQUARDT AND GREG SACHS.

9. Other records which substantiate this date are as follows: SUBSEQUENT TELTECH LOCATED EXPERT, DR. JOHN MOORE, BIO-IMAGING RESEARCH, INC., AND TELEPHONE REPORTS AND LETTER FROM DR. MOORE, (BETWEEN 10-31-89 AND 12-21-89), ON RADIOGRAPHIC IMAGING AND MATERIALS.

10. This was read by me and I understand it. (Desirable to use person or persons to whom idea was first disclosed.)

Name Lionn M. Johnson Date March 12 1992

Name [illegible] Date 3/12/92

11. Submitted by: David W. Mayer Date February 20, 1992

Date

PROPRIETARY MATERIAL

B

SCHNEIDER

INTEROFFICE MEMO

April 1, 1992

To: J. Laptewicz

cc: J. Douglas, S. Healy, M. Jendro, G. Morrison, J. Quackenbush, B. Thatcher

From: A. Marquardt

Subject: MARCH MONTHLY REPORT

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Radiopacity:

The wire for the DFT enhanced radiopacity program is starting to come in. Both the 0.0047 and 0.0055 in 10% Tantalum wire is in stock. Wire has been braided and is undergoing wire spin fatigue analysis at this time. Twenty-five percent wire is due in within two weeks and the 45% coronary wire is due in early May. We are ordering the platinum wire for the small size coronary wire due to the inherent question of whether 45% Tantalum will compromise the mechanical and expansile properties of the stent. Biocompatibility specimens of the Tantalum/Elgiloy wire will be sent to NAmSA next week, with long-term implant results at one week, one month, three months, and six months.

If the 10 or 25% Tantalum core wires pass the mechanical testing, testing for a 510(k) for biliary will be complete in June. Biocompatibility will be the hold up for IDE submission as full tripartite GLP data is required. The reason biocompatibility could not be started sooner was because we could not obtain material processed in accordance with manufacturing techniques required by the stent. This is the first material (Elgiloy-cased DFT) of this type and spring temper developed at Fort Wayne.

REDACTED

ALM/ekn

M E M O

TO: Those listed* July 06, 1992

FROM: David Mayer, X5825 DWM

SUBJECT: MEETING WITH PROF. K. LARNTZ TO DISCUSS STENT FATIGUE LIFE CONFIDENCE INTERVALS AND SURVIVAL LEVELS, AND ENHANCED RADIOPACITY MATERIAL COMPARISON WITH ELGILOY

---

*	J. Douglas	J. Erb	M. Gaulke
	D. Kildahl	K. Lind	A. Marquardt
	J. McGrath	R. Olson	G. Sachs

DATE: FRIDAY 10 JULY 1992 **TIME: 10:30 a.m.**

PLACE: STENT BOARD ROOM

Please plan to attend this very important meeting. We will be focusing on the statistical presentation of stent wire fatigue life in the peripheral vascular IDE and implications for future submissions.

A related secondary topic will be the initial comparison analysis of the current Elgiloy solid wire fatigue with the Elgiloy "DFT" tantalum composite for radiopacity enhancement.

Schneider U.S. Stent Division
Pfizer Hospital Products Group
5905 Nathan Lane
Minneapolis, MN 55442
Tel 612 550 5500 Fax 612 550 5805

SCHNEIDER

FACSIMILE TRANSMITTAL COVER SHEET

✓ URGENT ___ REGULAR ___ CONFIDENTIAL

DESTINATION: NORTH AMERICAN SCIENCE ASSOCIATES, INC.

ATTENTION: MR. KIRK DAMMEYER

FROM: DAVID MAYER

==========

MESSAGE: KIRK - I UNDERSTAND FROM YOUR CUSTOMER SERVICES GROUP THAT MY FED EX BOX PACK HAS BEEN RECEIVED AT NAMSA AND FORWARDED TO YOUR AREA. THIS FAX IS TO HELP CLARIFY ANY CONFUSION I MAY HAVE CAUSED WITH PREFERRED IMPLANT SEQUENCE, (i.e., TANTALUM, ELGILOY, MP35N), AND MY ACCIDENTAL OMISSION OF THE "**180 DAY IMPLANT SERIES**" FOR THE MP35N COUPONS. WE ARE REQUESTING THAT YOU BEGIN IMPLANTS WITH THE TANTALUM SPECIMENS IN THE 180 DAY ANIMALS IF THERE IS ANY SIGNIFICANT SERIAL OR SEQUENTIAL DELAY IN COMPLETING THE FULL ANIMAL GROUP FOR EACH MATERIAL. ELGILOY® COUPONS SHOULD FOLLOW THE TANTALUM, AND MP35N® WILL BE THE THIRD IN PRIORITY.

ALSO ATTACHED IS A REVISED COPY OF THE "**GLP COMPLIANCE NOTIFICATION**" FORM FOR THE MP35N® SERIES WITH THE ADDITION OF THE 180 DAY STUDY SERIES. I APOLOGIZE FOR ANY INCONVENIENCE. BILL ROTH AND I ALSO DISCUSSED THE AVAILABILITY SEQUENCE FOR MY REMAINING FIVE (5) MATERIAL AND CONCLUDED WE WOULD LIKE TO KEEP THINGS TOGETHER AS A STUDY, BUT THAT I WILL HAVE THREE (3) ADDITIONAL MATERIALS TO NAMSA IN TWO TO FOUR WEEKS AND THE FINAL TWO (2) ITEMS MAY TAKE EIGHT TO TWELVE WEEKS. I WILL DO MY BEST TO KEEP YOU INFORMED OF ANY CHANGES. PLEASE CALL IF YOU REQUIRE ANY FURTHER CLARIFICATION. THANKS FOR YOUR ASSISTANCE.

BEST REGARDS, David W. Mayer

DAVID W. MAYER

P.S. TANTALUM GLP COMPLIANCE NOTIFICATION FORM WITH "(T35)" CORRECTION ALSO INCLUDED

DATE	TIME	REFERENCE NO.	FACSIMILE NO.	TOTAL NO. OF PAGES
08-04-92	1005 CDT		(419) 666- 2954	3

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E

HOSPITAL PRODUCTS GROUP

1991 MAJOR R&D PROJECTS

NOVEMBER 1990

Divisional Section

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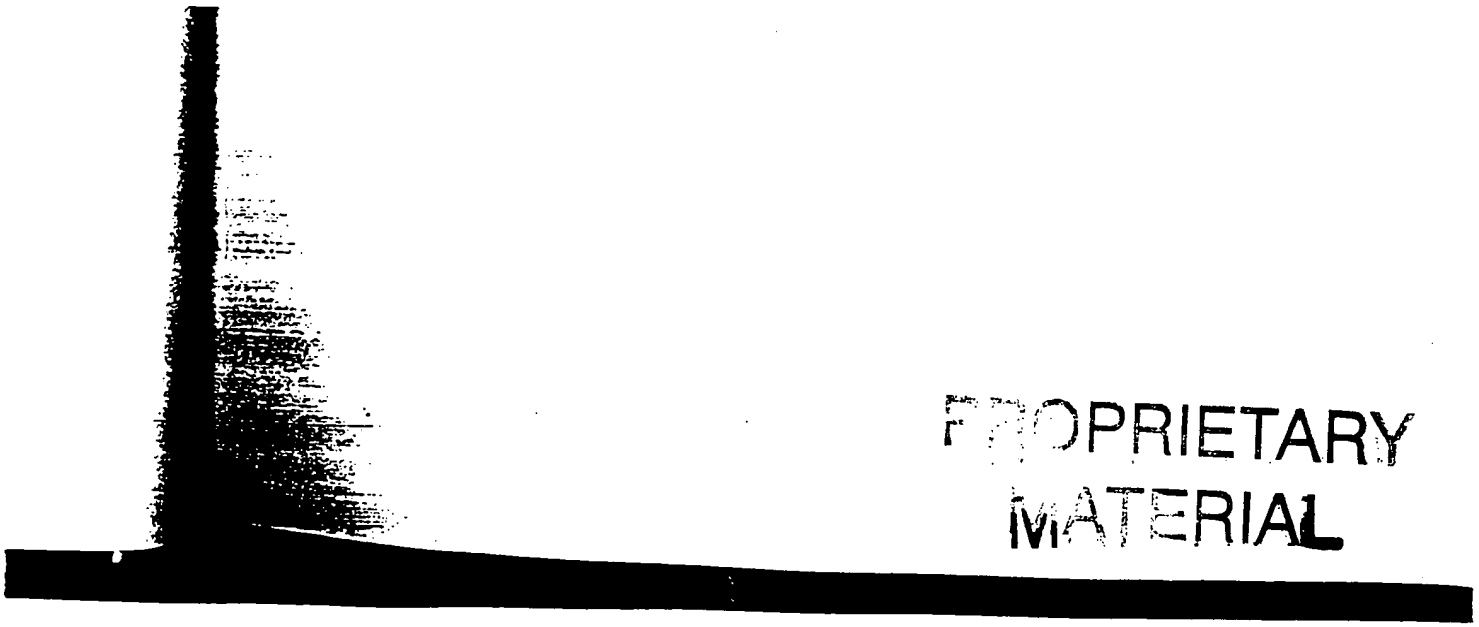

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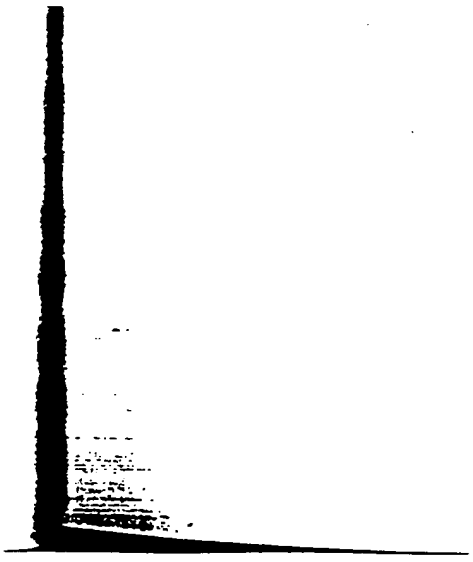

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C. Stent Visibility

The present stent is difficult to image on x-ray film and very difficult to distinguish using fluoroscopy.

1. Alternate stent materials:

Evaluation of material known to be more radiopaque as substitute stent materials. Significant challenges involve surface finishing and cleaning as well as suitable resilience to allow adequate deformation for loading onto deployment device.

2. Composite stent structure:

Coaxial layered wire composites will provide opportunity to create an outer ring of material chosen for biocompatibility and mechanical properties and an inner core chosen for radiopacity.

3. Alternate methods:

Evaluation of potential for using optical interference and cross-polarization will be conducted.

PROGRAM NAME: Stent Development (contd)

REDACTED

C. Radiopacity

1. Determine feasibility of alternate homogeneous materials. 1Q/91

2. Determine feasibility of coaxial wire structure with adequate physical, corrosive and radiopaque properties. 3Q/91

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PROGRAM NAME: Clinical Research (contd)

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PROGRAM NAME: Clinical Research (contd)

REDACTED

PROGRAM NAME: Clinical Research (contd)

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PROPRIETARY MATERIAL

TECHNOLOGY PROJECT DESCRIPTION

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PROPRIETARY
MATERIAL

PTCA Improvements (contd)

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SCHNEIDER

March 6, 1991

INTEROFFICE MEMO

To: Jon McGrath

From: Dave Mayer, X5825 cc: M.Gaulke, L.Johnson

Subject: FEBRUARY PRINCIPAL ACTIVITIES

REDACTED

3. Consulting p.o. with Peugeot Technologies, Inc. established for stent radiopacity.

4. Elgiloy• welded and drawn tubing ordered via E.L.P. for "DFT" stent material composite fabrication.
   - MP35N• proof-of-concept material being quoted
   - Elgiloy• drilled and filled composite being quoted

5. Elgiloy• wire spin fatigue testing progressing at Valley Instrument, Medinvent, and FWMRP Corp. with ø.0047 in. (ø.120mm) wire for ø10.0mm standard braid stent.

6. All Valley Instrument Elgiloy• runouts (22) with ruptured specimens (16) reported to Larntz for statistical evaluation.
   - Phynox• ø.0047in. (ø.120mm) testing begun

7. Phynox•/Elgiloy• material inclusion books sent to E.L.P. and FWMRP Corp.
   - E.L.P. has requested a special Cartech triple melt of Elgiloy• via VIM/VAR/ESR for evaluations. (Book copies to Cartech delayed by non-disclosure agreement difficulties currently being resolved.)

REDACTED

MARCH GOALS

REDACTED

PROPRIETARY MATERIAL

3. Begin axial stent fatigue trials:
   - Peripheral vascular standard ø10mm stents.
   - Biliary standard ø10mm stents.
   - Biliary less shortening ømm stents.
   - Biliary less shortening ø10mm stents with tantalum radiopacity substitution.

4. Open tooling development contract for stent cutting demonstration fixture.

5. Update Larntz's ø10mm stent wire fatigue analysis for Elgiloy•.
   - Begin Larntz's ø5mm stent wire fatigue analysis for Phynox•

6. Send Elgiloy•/Phynox• inclusion books to Cartech and Medinvent/Imphy.

7. Order two Elgiloy• "DFT" configurations and MP35N• proof-of-concept composite materials.

REDACTED

DWM/pm

G

Schneider (USA) Inc
Pfizer Hospital Products Group
5905 Nathan Lane
Plymouth, MN 55442
Tel 612 550 5500 Fax 612 550 5771

SCHNEIDER

FACSIMILE TRANSMITTAL COVER SHEET

___ URGENT X REGULAR ___ CONFIDENTIAL

DESTINATION: FORT WAYNE METALS R.P. CORP.

ATTENTION: MR. SCOTT GLAZE / MR. BRAD BRADLEY

FROM: DAVE MAYER

MESSAGE: I'D LIKE TO ORDER THE FOLLOWING MP35N-Ta DFT WITH 60-65 % FINAL COLD REDUCTION:

1. Φ.0031 ± 0.0001 in. MP35N-10 Ta (% C.S.A.)
   5,000 ft. min., 0.15-0.25 lb REF.
2. Φ.0031 ± 0.0001 in. MP35N-46 Ta (% C.S.A.)
   5,000 ft. min., 0.20-0.30 lb REF.
3. Φ.0047 ± 0.0001 in. MP35N-10 Ta (% C.S.A.)
   7,200 ft min., 0.50-0.60 lb REF.
4. Φ.0047 ± 0.0001 in. MP35N-46 % Ta (% C.S.A.)
   7,200 ft min., 0.60-0.70 lb REF.

Ta IS REQUESTED IN ACCORDANCE WITH ASTM F560, UNS R05200, CHEM. MULTIPLE SPOOLS/SIZE - % COMPOSITION ACCEPTABLE WITH MINIMUM 500 ft/SPOOL. CAN YOU QUOTE ME BEFORE 12:00 PM 4-30-91? PLEASE CALL WITH QUESTIONS, 612-550-5825.

DATE	TIME	REFERENCE NO.	FACSIMILIE NO.	TOTAL NO. OF PAGES
04-29-91	1730 CDT		(219)	1

PLEASE CALL IF THE TOTAL NUMBER OF PAGES ARE NOT RECEIVED

NRC INC.
NEWTON, MA U.S.A.

JUN - 5 1990
FORT WAYNE METAL
FORT WAYNE, INDIAN

TANTALUM MATERIAL CERTIFICATION

UNS [illegible]

Customer: [illegible]
P.O. No.: [illegible]
NRC Order No.: [illegible]

Date: [illegible]
Material: [illegible]
Condition: [illegible]

Item	Pcs.	Description	Weight	Ingot
1	[illegible]	[illegible]	[illegible] lb	[illegible]

Contract #1
"Tantalum" JBK 6-7-90

LOT NO. NRC-1009

Guaranteed to Conform to SPECIFICATION: ASTM F-560

CHEMICAL ANALYSIS IN PPM

Ingot	O	N	C	H	Fe	Ni	Cr	Ca	Cu	Si	Ti	Mo	W	Nb
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

MECHANICAL TEST RESULTS

Item/ Ingot	UTS KSI	.2%YD KSI	%Elong	Grain Size	Hardness	Bend Test	%Tube Flare	FINAL PRODUCT CHEMIS O	N	C
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

NON-DESTRUCTIVE TEST RESULTS

Unit Hydro: psi for Minutes.
Tube Hydro: psi
Reverse Flatten:
Helium Leak Test @ cc/sec.
Penetrant Examination:

PROPRIETARY MATERIAL

NRC QUALITY ASSURANCE DEPT.

Schneider (USA) Inc
Pfizer Hospital Products Group
5905 Nathan Lane
Plymouth, MN 55442
Tel 612 550 5500 Fax 612 550 5771

SCHNEIDER

FACSIMILE TRANSMITTAL COVER SHEET

___ URGENT X REGULAR ___ CONFIDENTIAL

DESTINATION: FORT WAYNE METALS

ATTENTION: MR SCOTT GRAZE

FROM: DAVID MAYER

MESSAGE: SIGNED-OFF AND NUMBERED P.O. ATTACHED. PEG BOLAN RETURNS 05-09-91 WITH CONFIRMING PAPERWORK FOLLOWING. THANKS!

-DLMayer

DATE	TIME	REFERENCE NO.	FACSIMILIE NO.	TOTAL NO. OF PAGES
05/07/91	1648			2

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Pfizer SCHNEIDER

PURCHASE REQUISITION

PURCHASE ORDER NO. [redacted]

C/O# [redacted]

MAY 0 8 1991

SHADED AREAS TO BE COMPLETED BY PURCHASING ONLY

VENDOR: Ft. Wayne [redacted]

VENDOR #: [redacted]25210

TERMS: [redacted] 1/30

SHIP VIA: [redacted] FOB

DELIVERY DATES: [redacted] Prel 12

CONTACT: Scott Glaze PHONE: [redacted]

NOTES: [redacted]

JUSTIFICATION: PROTOTYPE STENT MATERIAL OF RADIO-ENHANCED COMPOSITE WIR

SUGGESTED SUPPLIER: FORT WAYNE METALS RES. PROD. CORP

PO. BOX 9040

FT. WAYNE IN 46899

CONTACT: MR. SCOTT GLAZE PHONE: (219) 747-4154

ITEM	QTY.	U/M	PART NO.	DESCRIPTION	ESTIMATED UNIT PRICE	ACTUAL UNIT PRICE	EXTENDED COST
				Drawn Filled Tubing (DFT) fabricated from MP35N (ASTM F 562, chemistry only) seamless tube stock		[redacted]	[redacted]
				and a Tantalum core (ASTM F 560, R05200 Electron Beam or Vacuum Cast, chemistry only). Each of		[redacted]	[redacted]
				the following items are to be cold drawn with a final reduction of 60-65 percent cross sectional		[redacted]	[redacted]
				area (CSA):		[redacted]	[redacted]
1	1	LOT		ø.0031 +/-0.0001 in. Dia., 10 percent core CSA, 5,000 ft. minimum, 0.15-0.25 lb. REFERENCE.	$500.00	[redacted]	[redacted]
2	1	LOT		ø.0031 +/-0.0001 in. Dia., 46 percent core CSA, 5,000 ft. minimum, 0.20-0.30 lb. REFERENCE.	$600.00	[redacted]	[redacted]
3	1	LOT		ø.0047 +/-0.0001 in. Dia., 10 percent core CSA, 7,200 ft. minimum, 0.50-0.60 lb. REFERENCE.	$1,200.00	[redacted]	[redacted]
4	1	LOT		ø.0047 +/-0.0001 in. Dia., 46 percent core CSA, 7,200 ft. minimum, 0.60-0.70 lb. REFERENCE.	$1,600.00	[redacted]	[redacted]
				Please apply best effort to achieve maximum cast diameter with minimum lift. Multiple spools with a minimum of 500 feet/spool are acceptable.		[redacted]	[redacted]
				PLEASE SPLIT ORDER AND RUSH DELIVERY IF CERTAIN ITEMS COMPLETE PROCESSING EARLY.		[redacted]	[redacted]
						[redacted]	[redacted]
						[redacted]	[redacted]

REQUISITION NO. S 9152

ITEM	DEPT.	ACCT. NO.	ITEM	DEPT.	ACCT. NO.
1	827	939	4	8287	939
2	827	939			
3	827	939			

ER# CPA#

REQUESTED BY: [redacted] EMPLOYEE #: [redacted]

DEPARTMENT: 827 STENT DATE REQUIRED: 08/09/91

TEL. EXT.: 5825 DATE: 05/07/91 Q.A. INSP. REQ'D: ☐ Yes ☒ No

PURCHASE: [redacted] REQUISITIONER

SIGNATURE APPROVALS [redacted] DATE [redacted]

5-7-91

PROPRIETARY MATERIAL

DO NOT FILL IN SHADED AREAS

Pfizer SCHNEIDER

PURCHASE REQUISITION

PURCHASE ORDER NO. 26953 [redacted] 953

C/O# -

SHADED AREAS TO BE COMPLETED BY PURCHASING ONLY

VENDOR:	VENDOR #:	JUSTIFICATION: PROTOTYPE STENT MATERIAL OF
	TERMS:	RADIO-ENHANCED COMPOSITE WIRE
	SHIP VIA:	SUGGESTED SUPPLIER: FORT WAYNE METALS RES. PROD. CORP.
	DELIVERY DATES:	P.O. BOX 9040
CONTACT: PHONE:		FT. WAYNE, IN 46899
NOTES:		CONTACT: PHONE: MR SCOTT GLAZE (219) 747-4154

ITEM	QTY.	U/M	PART NO.	DESCRIPTION	ESTIMATED UNIT PRICE	ACTUAL UNIT PRICE	EXTENDED COST
				Drawn Filled Tubing (DFT) fabricated from MP35N (ASTM F 562, chemistry only) seamless tube stock			
				and a Tantalum core (ASTM F 560, R05200 Electron Beam or Vacuum Cast, chemistry only). Each of			
				the following items are to be cold drawn with a final reduction of 60-65 percent cross sectional			
				area (CSA):			
1	1	LOT		ø.0031 +/-0.0001 in. Dia., 10 percent core CSA, 5,000 ft. minimum, 0.15-0.25 lb. REFERENCE.	$500.00		
2	1	LOT		ø.0031 +/-0.0001 in. Dia., 46 percent core CSA, 5,000 ft. minimum, 0.20-0.30 lb. REFERENCE.	$600.00		
3	1	LOT		ø.0047 +/-0.0001 in. Dia., 10 percent core CSA, 7,200 ft. minimum, 0.50-0.60 lb. REFERENCE.	$1,200.00		
4	1	LOT		ø.0047 +/-0.0001 in. Dia., 46 percent core CSA, 7,200 ft. minimum, 0.60-0.70 lb. REFERENCE.	$1,600.00		
				Please apply best effort to achieve maximum cast diameter with minimum lift. Multiple spools with a minimum of 500 feet/spool are acceptable.			
				PLEASE SPLIT ORDER AND RUSH DELIVERY IF CERTAIN ITEMS COMPLETE PROCESSING EARLY.			

REQUISITION NO. S 9152 Taxable ☐ Non-Taxable ☐ TOTAL $

ITEM	DEPT.	ACCT. NO.	ITEM	DEPT.	ACCT. NO.
1	827	939	4	827	939
2	827	939			
3	827	939			

ER# CPA#

REQUESTED BY: David W. Mayer EMPLOYEE #: 888

DEPARTMENT: 827 STENT DATE REQUIRED: 08/09/91

TEL. EXT.: 5825 DATE: 05/07/91 Q.A. INSP. REQ'D.: ☐ Yes ☒ No

PURCHASED BY: P.O. DATE:

SIGNATURE APPROVALS	DATE
[signature]	5-7-91

PURCHASING

DO NOT FILL IN SHADED AREAS

Pfizer SCHNEIDER

PURCHASE REQUISITION

PURCHASE ORDER NO. 26953 3 953

C/O#

SHADED AREAS TO BE COMPLETED BY PURCHASING ONLY

VENDOR:	VENDOR #:	JUSTIFICATION: PROTOTYPE STENT MATERIAL OF
	TERMS:	RADIO-ENHANCED COMPOSITE WIRE
	SHIP VIA:	SUGGESTED SUPPLIER: FORT WAYNE METALS RES. PROD. CORP.
	DELIVERY DATES:	P.O. BOX 9040
CONTACT: PHONE:		FT. WAYNE, IN 46899
NOTES:		CONTACT: PHONE: MR SCOTT GLAZE (219) 747-4154

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				Please apply best effort to achieve maximum cast diameter with minimum lift. Multiple spools with a minimum of 500 feet/spool are acceptable.			
				PLEASE SPLIT ORDER AND RUSH DELIVERY IF CERTAIN ITEMS COMPLETE PROCESSING EARLY.			

REQUISITION NO. S 9152 Taxable ☐ Non-Taxable ☐ TOTAL

ITEM	DEPT.	ACCT. NO.	ITEM	DEPT.	ACCT. NO.
1	827	939	4	8287	939
2	827	939			
3	827	939			

SIGNATURE APPROVALS	DATE
	5-7-91

ER# CPA#

REQUESTED BY: David W. Mayer EMPLOYEE #: 688

DEPARTMENT: 827 STENT DATE REQUIRED: 08/09/91

TEL. EXT.: 5825 DATE: 05/07/91 Q.A. INSP. REQ'D.: ☐ Yes ☒ No

PURCHASED BY: P.O. DATE:

PURCHASING

PROPRIETARY MATERIAL

05/07/01 15:44 FAX 612 550 5805 SCHNEIDER STENT 001

ACTIVITY REPORT

TRANSMISSION OK

TRANSACTION #	3986
CONNECTION TEL	0 1 218 747 0398
CONNECTION ID	FT WAYNE METALS
START TIME	05/07 15:41
USAGE TIME	02'54
PAGES	2

[redacted]

SCHNEIDER June 3, 1991

INTEROFFICE MEMO

TO: Jon McGrath

FROM: Dave Mayer

SUBJECT: MONTHLY SUMMARIES: MARCH, APRIL, MAY, 1991

March

- Stent fatigue testing and F.E.A. support for peripheral vascular IDE submission.
- Statistical fatigue analyses with Prof. K. Larntz for wire spin fatigue data.
- S. Landsman consultations on the connection between fatigue safety factor and Goodman diagram statistical confidence intervals.
- Dr. Outwater contacted at VICO for alternative wire spin fatigue machine design to saline test material.
- R. Homewood assisted at Groton, CT, with instron axial tension-tension wire fatigue testing demonstration. Unsuccessful at Metcut Research due to clamping wire breakage.

April

- ϕ5mm Nivarox Phynox® peripheral stents entered axial elongation testing for fatigue to 10,000,000 cycles.
- Stent cutting fixture contract initiated with K.C. Kessel and TMC Tool for June 7, 1991, tool demonstration.
- Medinvent/Sprint Metal visited.
- Society for Biomaterials annual convention attended.
- Corrosion axial fatigue test performed on single and double tantalum substituted biliary stents.

May

- Society for Biomaterials annual convention attended.
- Made contact with Prof. Stan Brown, Case Western Reserve University, regarding his original corrosion testing performed on WALLSTENT® material, Phynox®. He claimed no payment was ever received, I am checking Schneider accounting records. We discussed the difference between stress corrosion testing, corrosion fatigue testing, and accelerated testing.
- Made contact with Drs. Kossowsky and Kossovsky regarding Elgiloy® aneurysm dip work they published. They had no knowledge of any stress corrosion or corrosion fatigue data from their earlier work or any other sources.
- Ordered MP35N DFT from FWMRP Corp with 10% and 46% tantalum cores. This interim concept evaluation material at ϕ.0031 in. and ϕ.0047 dias. before Elgiloy® tubing is available to convert to DFT in July.
- Received first report from Peugeot Technologies on critical radiography parameters of DFT candidate materials. Advised him of further test needs and he is amending for beginning of June.
- Sample platinum alloy wire requests confirmed at Johnson Mathey and Sigmund Cohn as alternate core stocks. Alloys include Pt-20%Ir, Pt-10%Ni, and Pt-8%W. Will assess mechanical properties by tensile test, torsional moduli, and preliminary wire spin fatigue.

- Initiated C.Clerc ϕ10mm gold plated biliary stent corrosion axial fatigue test to 1,000,000 cycles. Conclude first week of June and analyze at Alliant Techsystems, Inc.
- Completed initial S.E.M. surveys of tantalum substituted stents subjected to 1,000,000 cycles corrosion axial fatigue test. No evidence of saline corrosion. Some mechanical ductile abrasive wear, i.e. micro-contact pressure welding, or galling, with fretting.
- Completed JK inclusion surveys with Elgiloy® Limited Partnership for new stent wire stock melt source. Heat is identified as Imphy S.A. WG435, approximately 59 pounds. Shipment planned to FWMRP Corp by end of June.
- Concluded Prof. K. Larntz's re-evaluation of fatigue statistics models and confirmed the use of the lognormal model and data pool segregation, i.e. Medinvent from Schneider Stent and Valley Instrument data pooled data.
- Completed strain hardening assessments to support peripheral I.D.E. submission on ϕ5 and ϕ10mm fatigue cycled stents (10,000,000 cycles). Alliant Techsystems, Inc. performed microhardness testing and found no evidence of any straining and hardening due to repeated stent deformations.

June Goal Activities

Urgent priorities:
- L. Johnson performance appraisal.
- Development engineer job description and posting.
- Interviews
- Saline fatigue testing of ϕ.0035 in. wire.
- Update radiopacity project schedule.
- NOTE: Informed 5/31 that stent cutting fixture tolerance buildup will delay 6/7 demonstration date out to 6/28.

Ongoing work:
- Stent wire material specification review copies circulated.
- Fatigue testing of biliary wire.
- Fatigue testing of DFT prototypes.
- Protocol for axial tension-tension fatigue test at Groton, Ct.
- Coronary stent design optimization by F.E.A.
- General stent bench characterization by weighted displacement, ϕ5-ϕ10mm sizes, for F.E.A. correlation.

DWM/pm

cc: M. Gaulke
L. Johnson

SCHNEIDER STENT

LABORATORY TEST REQUEST

KEY WORDS: STENT RADIOPACITY, ELGILOY®, TANTALUM WIRE SUBSTITUTION, AXIAL ELONGATION FATIGUE, BILIARY, LESS-SHORTENING BRAID, TD0032 REF, BIMETALLIC GALVANIC CORROSION, NORMAL SALINE, BODY TEMPERATURE (37°C)

PROJECT NO.	PROJECT TITLE	TEST NO.	REV.	PAGE OF
	BILIARY STENT ENHANCED RADIOPACITY TANTALUM WIRE SUBSTITUTION			1 / 1

TITLE OF TEST	DATE OF REQUEST	EST. START DATE
STENT AXIAL ELONGATION FATIGUE TEST IN NORMAL SALINE AT 37°C WITH S.E.M./E.D.S. ANALYSIS OF WEAR AND BIMETALLIC CORROSION POTENTIAL	04-15-91	04-15-91

ORIGINATOR	TECHNICIAN	PROJECT ENGINEER	MGR. APPROVAL
D. Mayor	L. JOHNSON / M. GAULKE	D. MAYER	

MATERIAL	LOT # / HT. NO.	VENDOR
ELGILOY® Ø.0055 in DIA. TANTALUM Ø.0055 in DIA (ASTM F560-B05400)	ELGILOY: E2007 / HT. NO. 85433 T2: 11846/1352A	ELGILOY: FLWIRP GRP./CARTECH T2: CALIFORNIA FINE WIRE CO.

RATIONALE FOR TEST: TO EVALUATE THE MECHANICAL FATIGUE CHARACTERISTICS OF STENT WITH TANTALUM WIRE SUBSTITUTION OF ONE AND TWO ELGILOY® BRAID WIRES. ALSO EVALUATE THE BIMETALLIC GALVANIC AND FRETTING CORROSION POTENTIAL AT BRAID OVERLAYS OR PICKS.

TEST OBJECTIVE AND DESCRIPTION: PERFORM AXIAL FATIGUE IN SCHNEIDER STENT TEST FIXTURE. STENT DIAMETER WILL CYCLE ± 1.0 MM ABOUT Ø9.0 MM PRESTRESS DIAMETER REDUCTION FROM Ø10.0 MM RESTING DIAMETER. STROKE WILL BE SET IN ACCORDANCE WITH TWO PITCH CYCLES BETWEEN BEVELLED SHOULDERS OF DELRIN MOUNTING STUBS. MAXIMUM TEST DURATION WILL BE 500,000 CYCLES FOR FULL ENDURANCE TEST SPECIMENS SHOWING NO WIRE BREAKAGE. CYCLE RATE WILL BE 1.0 Hz. INTERMEDIATE CYCLE COUNT SPECIMEN RETRIEVAL WILL BE AT 1,000; 10,000; AND 100,000 CYCLES, OR EARLIER IF WIRE BREAKAGE IS EVIDENCED. TOTAL OF FOUR SINGLE AND FOUR DOUBLE T2 WIRE SPECIMENS WILL BE EVALUATED IN THIS PRELIMINARY "RANGE-FINDING" TEST. STATIC CLAMPED AREAS OF EACH SPECIMEN WILL SERVE AS WEAR/CORROSION CONTROL SAMPLES. WEIGH SPECIMENS BEFORE AND AFTER TESTING. PERFORM S.E.M./E.D.S. ANALYSIS TO DETERMINE ANY WEAR MORPHOLOGY, FATIGUE FAILURE, OR CORROSION BEHAVIOR.

SENSITIVITY REQUIRED	ACCURACY REQUIRED
S.E.M. EVALUATION 10X TO 25,000X AS NECESSARY TO IMAGE FEATURES.	STENT WEIGHING TO 0.0002 g

COMMENTS: 1.0 PITCH CYCLE = 31.9 MM (1.256 in.), 2 x PITCH = 63.8 MM (2.512 in.) AT O.D. CONSTRAINED OF Ø8.0 MM (Ø.315 in.) MIN

1.0 PITCH CYCLE @ Ø10.0 MM (Ø.394 in.) = 23.5 MM (0.928 in.), 2 x PITCH = 46.5 MM (1.831 in.) MIN Dr. MIN

* LJLB # 30 p 88

* MG #34 pg 26-45, 47-56

c:

TEST REFERENCE 000093

FM0026-2

INVENTION DISCLOSURE

1. NAME, HOME ADDRESS, AND TITLE OF INVENTOR -

KEVIN R. HEATH
44 WAGNN AVE
PROVIDENCE, RI 02908

2. TITLE OF INVENTION -

NITINOL WIRE MADE TO BE RADIOPAQUE

3. IMPORTANT DATES -

A. Date of conception of the Invention 1/25/91

B. Date of reduction to practice

C. Date of any written reports or publications 1/25/91 informal ESD notebook

D. Date of disclosure of invention to anyone outside the company 1/28/91

E. Date of sale of any item embodying the invention

Disclosed to and understood by me this 29 day of MARCH, 1991

Patricia McCluskey
Signature of Witness

Ken R Heath
Signature of Inventor

3/29/91
Date

4. STATE PURPOSE OF THE INVENTION IN BRIEF, GENERAL TERMS -

To make the nitinol wire visible under x-ray or flouroscopy. Using this wire to knit a stent or to make a guidewire would make these devices radiopaque

Disclosed to and understood by me this 29 day of MARCH, 1991

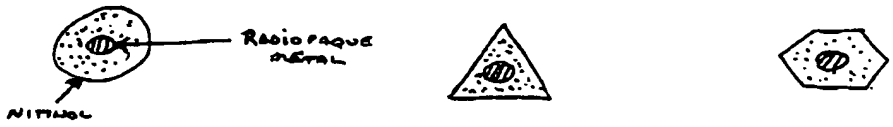
Patricia McCarthy
Signature of Witness

Kevin J Boyle
Signature of Inventor

3/29/91
Date

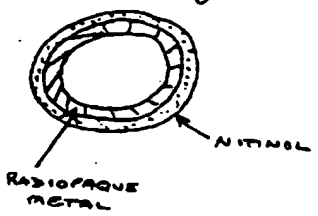
7. DESCRIBE IN DETAIL THE STRUCTURE AND OPERATION OF THE INVENTION. INCLUDE REFERENCES TO ATTACHED SKETCHES IF NECESSARY.

The construction is of a solid, or perhaps non-solid, cross section of Nitinol where WITHIN its cross section there exists a solid cross section of a RADIOPAQUE METAL. This additional metal will make the Nitinol cross section radioscopically, fluoroscopically visible. These cross sections can be drawn, as with wire etc., in a continuous lengths.



etc.

You can see that the outer shapes & inner shapes of the 2 metals can be many. They could also include tubing cross sections.



Disclosed to and understood by me this 29 day of MARCH, 1991

Patricia McCluskey
Signature of Witness

Ken A Heath
Signature of Inventor

3/29/91
Date

7) (Continued)

The nominal radiopaque metal's cross-section is determined by its density; proportionate to its visibility: Obviously there must be enough material present in its cross section to make it visible. So therefor functional.

Potential materials:

Tantalum
Tungsten
Rhenium
Iridium
Silver
Gold
Platinum

These listed may be the most available practicle. The sole door choice will be determined by many factors some including; density, hardness, elasticity, availibility, cost, & manufacturability, & Thermal properties.

Patricia McCausley
WITNESS

Ken A. Hall
3/29/91
INVENTOL

8. SUMMARIZE THE FEATURES OF THE INVENTION WHICH YOU BELIEVE TO BE OF PARTICULAR SIGNIFICANCE -

Makes vitreal radioscopically & fluoroscopically visible even in small cross-sectional shapes. May elevate galvanic interactions, significantly, when applied to implantable devices. In the stent applications, it may be a less expensive alternative to other possible methods of making a stent visible (ie co-knitting a nitinol stent with tantalum wire) It may also improve it's "un-deployed" profile enabling a smaller delivery system.

9. STATE THE ADVANTAGES OF THE INVENTION OVER THE OLD MEANS AND METHODS DESCRIBED EARLIER -

Refer to # 8

Disclosed to and understood by me this 29 day of MARCH, 1991

Patricia McCloskey
Signature of Witness

Ken A Heath
Signature of Inventor

3/29/91
Date

10. INDICATE ALTERNATE METHODS OF CONSTRUCTION, AND/OR PERMISSIBLE RANGES, ETC.

- MULTIPLE OUTER CROSS-SECTIONAL SHAPES.
  ROUND, TRIANGULAR, DIAMOND, TRAPAZOIDAL, OCTAGONOL, HEXAGONAL etc
- MULTIPLE INNER CROSS-SECTIONAL SHAPES.
  NITINOL CROSS SECTION DOES NOT HAVE TO BE SOLID.
- COULD ALSO ALSO INCLUDE LAYERS OF NITINOL W/ LAYERS OF RADIOPAQUE METAL
- Could include other metals for the outer cross section

NOTE: After this disclosure has been completed, each sheet of the disclosure, including the sketches and other attachments, should be signed by the inventor and then read and signed by a witness, as indicated at the bottom of each sheet.

Disclosed to and understood by me this 29 day of MARCH, 19 91

Patricia McCluskey
Signature of Witness

Ken A Heath
Signature of Inventor

3/29/91
Date

TITLE 1/25/91 NiTi [illegible] RADIOPACITY IMPROVEMENTS Book No.

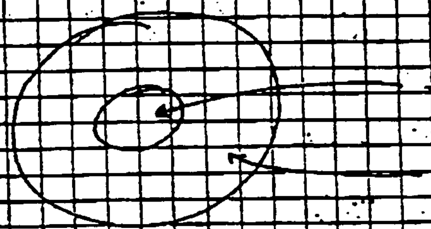
From Page No.

Radiographic examination suggest that nitinol wire is not quite equal to that of stainless steel (304 SS)

Marketing input has been increasingly pushing to make the wire more visible, radiographically

One Alternative:

draw wire that is a co-axial design containing a core of "safe" radiopaque metal with outer layer having of Nitinol [illegible] as x-sect area to maintain present elastic-flexural properties



present [illegible] area: .0000125 in²

To Page No.

Witnessed & Understood by me,	Date	Invented by	Date
[signature]	1/28/91	Kevin R Heath	1/25/91
		Recorded by [signature]	1/25/91

From Page No.___

Refer to Patent file # 91-104

Contains a basic patent disclosure [illegible] [illegible] 29, 1991

Memo "[illegible]" of a Mtg April 1, 1991

Early thoughts are to patent the concept of a radiopaque wire made by a radiopaque inner core & a "non-radiopaque" outer core.

One particular particular application is with nickel [illegible] wires under ~.0[illegible]" diameter but could easily be applied to other non-radiopaque metals

e.g. Stainless, steel & radiopaque filler Ta, W, Ag

I have included a list of potential outer & inner materials.

We may also want to patent the different products that B.S.C. could make out of this concept of a Radiopaque metallic core within a metal outer layer

e.g. radiopaque [illegible] hypotube ?

To Page No.___

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Project No.
Book No. TITLE

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Inside Materials:

		density	E	
	OSMIUM	22.48 g/cc	560 GPa	
	IRIDIUM	22.42	520 GPa	
*	PLATINUM	21.45	22.6-24.5 x 10^6 psi	
*	RHENIUM	21.20	460 GPa	
*	TUNGSTEN	19.3	410 GPa	
*	GOLD	19.3	10.8-11.6 x 10^6 psi	
N/A	URANIUM	19.05		[illegible]
*	TANTALUM	16.6	186 GPa	
N/A	MERCURY	13.55	—	
	HAFNIUM	13.09	—	
	RHODIUM	12.44	310-379 GPa	
	PALLADIUM	12.02	16.3 x 10^6 psi	
	THALLIUM	11.85	—	
	[illegible]	[illegible]		
N/A	LEAD	11.34	—	
*	SILVER	10.49	10.3 x 10^6 psi	
*	BISMUTH	9.9	32 GPa	

* More probable metals for medical applications

other conversions:

1 psi = 6.895 kPa
1 kPa = .145 psi
1 MPa = .145 ksi

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Recorded by

TITLE ____ Project No.____ Book No.____ 97

From Page No.____

Outside	Layers
Erbium	9.16
Copper	8.96
Nickel	8.90
Cobalt	8.92
Cadmium	8.65
Niobium	8.57
N/A — IRON	7.87
Manganese	7.44
Tin	7.3
Indium	7.31
ZN	7.14
Cr	7.14
Neodymium	7.0
Samarium	6.93
Cerium	6.78
Antimony	6.68
Zirconium	6.5
Tellurium	6.24
Lanthanum	6.19
Vanadium	6.11
Gallium	5.97
N/A — Arsenic	5.73
Germanium	5.32
Europium	5.24
~~Beryllium~~ Selenium	4.81
* Titanium	4.5
Yttrium	4.34
* Barium	3.5
Aluminum	~~2.6~~ 2.7
Strontium	~~2.3~~ 2.6
Boron	2.34
Silicon	2.32
Beryllium	1.84
Magnesium	1.74
Calcium	1.55
Sodium	0.97
Potassium	.86
LITHIUM	.53

To Page No.____

Witnessed & Ui... Date

Project No.______
Book No.______ TITLE ______

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These materials were selected on the general basis of density & perceived biocompatibility

Some of the same metals are presently used for medical device radiopacity applications.

- Ta (Tantalum)
- Au (Gold)
- Hf (Hafnium)
- Bi (Bismuth)
- Ba (Barium) — possible alloying as density filler within my personal metal [illegible]

But other materials are possible if the processing & biocompatibility is addressed pertaining to their use in medical product.

Both groups (inner & outer) contain a wide selection of metals all with different mechanical, biomechanical & [different] product manufacturability / assembly requirements & this will allow a "mix & match" approach depending on the performance criteria needed (stiffness, strength)

To Page No.___

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[signature]	5/17/91	Recorded by [signature]	5/17/91